

### Missouri Environmental Public Health Tracking (EPHT) Network

Metadata Record

# Birth Defects Data

# **Description**

#### Citation

**Title:** Missouri Birth Defects Nationally Consistent Data and Measures (NCDM) data for calendar years 2001-2006.

Originators: Missouri EPHT Program

Publication date: 05/03/2010

### **Description**

**Abstract:** Birth Defects data for Missouri residents for 2001-2006, according to the specifications of the Indicator Template and the Content Domain. More information regarding the creation of this indicator can be found in the Missouri EPHT Data and Statistical Guide available at <a href="http://www.health.mo.gov/living/environment/epht/index.php">http://www.health.mo.gov/living/environment/epht/index.php</a>.

**Purpose:** This dataset is required by the Centers for Disease Control and Prevention for submission to the EPHT Network.

**Supplemental information:** This dataset was extracted from the Missouri birth defect registry. The Department of Health and Senior Services (DHSS) maintains a birth defects registry for Missouri resident live births based on linkage of defects reported on birth certificates, death certificates, hospital patient abstracts, enrollment data for state programs to assist affected families, such as the Hope program (formerly Children with Special Health Care Needs); and screening data such as the newborn hearing screening data set. Cases include defects diagnosed and reported through the first year of life. The registry includes data for all births in the state, but is not complete for some counties in which a substantial proportion of residents use out-of-state hospitals. While birth and death certificates are available for Missouri residents using out-of-state hospitals, DHSS has limited access to patient abstract data from these hospitals.

Births since 1980 are included in the data set. Because of changes in access to data sets, and changes in data items included in each component data source, there are inconsistencies over time. For most investigations, DHSS prefers to limit studies to births since 1993.

The data for a calendar year of births are generally available 20 months after the close of

the year. The delay is necessary because cases are ascertained through the first year of life.

Birth defect registry data are used to monitor the health status of Missourians, particularly in areas potentially affected by environmental contamination. The data are also used to assist public health and educational officials in the development and conduct of programs to assist affected families, and to assist families in gaining access to state services.

The birth defects registry is a compilation of birth defects reported on live birth certificates, infant death certificates, newborn and pediatric patient abstracts, and program and screening data such as the Hope program and newborn hearing screening data. Select data elements from each data source are retained in the birth defects registry, with access to other data elements when required. Data elements from each source are listed below.

- Birth Certificate
  - The birth defects registry is based on the birth certificate. Birth defects reported on the birth certificate and all other data elements from that data set are part of the birth defects registry. A listing of birth certificate data elements is available at <a href="http://health.mo.gov/data/livebirths/dataelements.php">http://health.mo.gov/data/livebirths/dataelements.php</a>.
- Death Certificate
  - For all deaths within the first year of life, cause of death (ICD-10-coded) and age at death are included in the registry, however, access to all death certificate data items is available as needed. A listing of death certificate data elements is available at <a href="http://health.mo.gov/data/deaths/dataelements.php">http://health.mo.gov/data/deaths/dataelements.php</a>.
- Newborn and Pediatric Patient Abstracts
   For all inpatient and outpatient hospital encounters within the first year of life, routinely available data items are all reported diagnoses (ICD-9-CM-coded); admission and discharge dates; and type of hospital encounter (inpatient, outpatient, or emergency room). Access to all patient abstract data items is available as needed. A listing of patient abstract data elements is available at <a href="http://health.mo.gov/data/patientabstractsystem/dataelements.php">http://health.mo.gov/data/patientabstractsystem/dataelements.php</a>.
- State Program/Screening Data
   Data elements available vary by program. All programs and screening data included diagnosis (coded in ICD-9-CM upon inclusion in registry) and date of enrollment/screening.

### **Point of Contact**

**Person:** Missouri EPHT Program Manager

**Organization:** Missouri Department of Health and Senior Services

Division of Community and Public Health Section for Environmental Public Health Bureau of Environmental Epidemiology **Phone:** 573-751-6102 **Fax:** 573-751-6041

Telecommunications Device or Teletypewriter (TDD/TTY) phone: 800-669-8819

Email: EPHTN@health.mo.gov

Address type: Mailing

Address: PO Box 570 City: Jefferson City State or Province: MO Postal code: 65102-0570 County: Cole County

Address type: Physical

Address: 930 Wildwood Drive

City: Jefferson City
State or Province: MO
Postal code: 65109
County: Cole County

### Data Type

**Native dataset environment:** The file was created using SAS 9.2 TS Level 1MO, and Altova XMLSpy 2008 Professional Edition ver. 2008 rel. 2 sp. 2., on the Windows XP\_PRO ver. 5.1.2600 platform.

#### Time Period of Data

**Beginning date:** 01/01/2001 **Ending date:** 12/31/2006

Currentness reference: Time Period End Date

Status

Data status: Complete

**Update frequency:** Annually

### **Key Words**

Theme: Health

Keywords: Birth Defects, baby, infant, birth, Anencephaly, Spina Bifida, Hypoplastic Left

Heart Syndrome, Tetralogy of Fallot, Transposition of the Great Arteries

(vessels), Cleft Lip, Cleft Palate, Hypospadias, Gastroschisis, Upper Limb Deficiencies, Lower Limb Deficiencies, Trisomy 21, Down Syndrome, ICD-9-CM Diagnosis code, hospitalization, inpatient, emergency, principal diagnosis, 029, Missouri, MO

Keyword thesaurus: None

Theme: Health

**Keywords:** Birth Defects

**Keyword thesaurus:** ICD-9-CM

Place: Location

Keywords: 029, Missouri, MO

**Keyword thesaurus:** FIPS 5-2 (State)

#### **Data Access Constraints**

Access constraints: Access to the records within this dataset requires permission from the Missouri Department of Health and Senior Services, Bureaus of Vital Records (BVR) and of Health Informatics (BHI). To request record level data (whether identified or deidentified) for research, a principal investigator must submit a completed Application for Missouri Vital Records or Patient Abstract System Data for Research Purposes. Users requesting access to record-level data should be aware that not all data elements included in the birth defects registry will be provided on data sets released to users outside the Department of Health and Senior Services.

More information on obtaining permission to view and/or use this dataset is available at <a href="http://www.health.mo.gov/data/policies.php">http://www.health.mo.gov/data/policies.php</a>.

**Use constraints:** Missouri State Statutes and Code of Regulations allow for the release of record level vital records data by the Missouri Department of Health and Senior Services. The below listed statutes only apply to vital events occurring within Missouri's borders. The records of vital events that occur to Missouri residents in other states are the property of the state where the events take place.

- 193.045.2(4), RSMo, authorizes the state registrar to provide to the state or local health agencies copies of or data derived from certificates and reports required under sections 193.005 to 193.325, deemed necessary for state or local health planning and program activities...such copies or data shall remain the property of the department and the uses made of them shall be governed by the state registrar.
- 193.245(1), RSMo, the department to disclose upon request, a listing of persons who are born or who die on a particular date, but no information from the record other than the name and date of such birth or death shall be disclosed.
- 193.245(2), RSMo, allows the department to authorize disclosure of information contained in vital records for legitimate research purposes.
- 193.255.4, RSMo, authorizes the state registrar, upon request by federal, state, local
  and other public or private agencies, to furnish copies or data of any other vital
  statistics... for statistical or administrative purposes upon such terms or conditions as
  may be prescribed by regulation, provided that such copies or data shall not be
  used for purposes other than those for which they were requested unless so
  authorized by the state registrar.
- 19 CSR 10-10.090 Access to Vital Records: (1) (B) 3. No data shall be furnished from records for research purposes until the state registrar of vital records has received and approved a formal request for the research project. (1) (B) 2. The term research means a systematic study designed to develop or contribute to generalizable knowledge. The term generalizable means to emphasize the general

character rather than specific details of, to formulate general principles or inferences from particulars. (1) (D) authorizes the state registrar or the local custodian – when deemed in the public interest and not for purposes of commercial solicitation or private gain – to furnish copies of records or data from records to public agencies administrating health, welfare, safety, law enforcement, education or public assistance programs and to private agencies approved by the state registrar.

- Under section 610.035, RSMo, the department is prohibited from disclosing any Social Security number of a living person unless such disclosure is permitted by federal law, federal regulation or state law. Section 208.120, RSMo prohibits the department from disclosing any information obtained by them in the discharge of their official duties relative to the identity of applicants for or recipients of benefits or the contents of any records (e.g., Medicaid, Food Stamps). Public assistance information can be provided on de-identified records only.
- 45 C.F.R. Part 160 and Part 164. Vital Records requestors for research or administrative purposes will only be provided access to the minimum information necessary to achieve their specific research or administrative requests. Requestors are prohibited from disclosing any information that would identify a person and are also prohibited from the re-release of the data provided.

Missouri State Statutes and Code of Regulations allow for the release of Patient Abstract System (PAS) data by the Missouri Department of Health and Senior Services. The Missouri Department of Health and Senior Services and other public health authorities are authorized to utilize PAS information for epidemiologic studies and for surveillance. Non-Missouri residents should contact the Missouri Department of Health and Senior Services for specific statues, rules, and regulations that may affect the release and/or use of data. The below listed statues apply to Missouri residents only.

- 192.067(1), RSMo, the department, for purposes of conducting epidemiological studies to be used in promoting and safeguarding the health of the citizens of Missouri ... is authorized to receive information from patient medical records.
- 192.067(2), RSMo, Medical information...may be released by the department only in a statistical aggregate form that precludes and prevents the identification of patient, physician, or medical facility except that medical information may be shared with other public health authorities and coinvestigators of a health study if they abide by the same confidentiality restrictions required of the department of health and senior services... The department of health and senior services, public health authorities and coinvestigators shall use the information collected only for the purposes provided ...
- 192.665(9), RSMo, "Patient abstract data", data submitted by hospitals which
  includes but is not limited to date of birth, sex, race, zip code, county of residence,
  admission date, discharge date, principal and other diagnoses, including external
  causes, principal and other procedures, procedure dates, total billed charges,
  disposition of the patient and expected source of payment with sources

- categorized according to Medicare, Medicaid, other government, workers' compensation, all commercial payors coded with a common code, self-pay, no charge and other.
- 192.667(7), RSMo, Information obtained by the department under the provisions of section 192.665 and this section shall not be public information...The department of health and senior services may authorize the use of the data by other research organizations pursuant to the provisions of section 192.067... The department shall not release data in a form which could be used to identify a patient. Any violation of this subsection is a class A misdemeanor.
- 19 CSR 10-33.010 Reporting Patient Abstract Data by Hospitals and Ambulatory Surgical Centers: (1)(A) Coinvestigator means any person or organization that applies to the department to be a coinvestigator of an epidemiological study; (C) Epidemiological study means research using patient abstract data to understand, promote or safeguard the health of a defined population. No marketing study or study designed to use data on a specific provider shall be considered an epidemiological study; (M) Public health authority means a federal, state or local governmental agency which has as its mission and responsibility the promotion and safeguarding of the public's health.
- 19 CSR 10-33.010 Reporting Patient Abstract Data by Hospitals and Ambulatory Surgical Centers: (12) Any person may apply to the department to be a coinvestigator of an epidemiological study using patient abstract data. A research protocol shall be submitted which includes all of the following: (A) A description of the proposed study; (B) The purpose of the study; (C) A description of the data elements needed for the study; (D) A description of a tape or a report if either is required; (E) A statement indicating whether the study protocol has been reviewed and approved by an institutional review board; (F) A description of data security procedures, including who shall have access to the data; and (G) A description of the proposed use and release of the data.
- 19 CSR 10-33.010 Reporting Patient Abstract Data by Hospitals and Ambulatory Surgical Centers: (13) The director of the department shall appoint a data release advisory committee composed of three (3) persons representing the health care industry and three (3) persons representing researchers and consumers. The advisory committee shall review all research protocols of persons applying to be a coinvestigator of an epidemiological study using patient abstract data. The advisory committee shall make a recommendation to the director whether the coinvestigator protocol should be accepted, accepted with conditions, or rejected. The committee shall consider: (A) The review made by the staff of the department; (B) Whether the proposed study meets the definition of an epidemiological study; (C) The potential for the coinvestigator or any other person to use the data for nonepidemiological purposes; (D) The professional expertise of the applicant to conduct the study; (E) The appropriateness of the proposed study design; (F) The willingness and ability of the applicant to protect the identity of any patient, physician or provider; and (G) The data security measures and final

- disposition of the data proposed.
- 19 CSR 10-33.010 Reporting Patient Abstract Data by Hospitals and Ambulatory Surgical Centers: (14) The coinvestigator shall agree to the confidentiality, security and release of data requirements imposed by the department and shall agree to the review and oversight requirements imposed by the department.
- 19 CSR 10-33.010 Reporting Patient Abstract Data by Hospitals and Ambulatory Surgical Centers: (15) Data released to the coinvestigator shall not be rereleased in any form by the coinvestigator without the prior authorization of the department. Authorization for subsequent release of the data shall be considered only if the proposed release does not identify a patient, physician or provider.
- 19 CSR 10-33.010 Reporting Patient Abstract Data by Hospitals and Ambulatory Surgical Centers: (16) The following data elements permit identification of a patient, physician or provider, and are not to be rereleased by a coinvestigator: patient name; patient Social Security number; any datum which applies to fewer than three (3) patients, physicians or providers; physician number; provider number; and a quantity figure if one (1) entity contributes more than sixty percent (60%) of the amount.
- 19 CSR 10-33.010 Reporting Patient Abstract Data by Hospitals and Ambulatory Surgical Centers: (17) The department shall release only those patient abstract data elements to the coinvestigator which the department determines are essential to the study. The Unique Physician Identification Number (UPIN) associated with any patient abstract data shall not be released to any coinvestigator. If the research being conducted by a coinvestigator requires a physician number, the department may create a unique number which is not the UPIN. The department shall not provide information which links the unique number to the name of the physician.
- 19 CSR 10-33.010 Reporting Patient Abstract Data by Hospitals and Ambulatory Surgical Centers: (18) No epidemiological study conducted with a coinvestigator shall be approved unless the department determines that: (A) The epidemiological study has public benefit sufficient to warrant the department to expend resources necessary to oversee the project with the coinvestigator; (B) The department has sufficient resources available to oversee the project with the coinvestigator; and (C) The data release advisory committee reviewed the study and the director of the department authorized approval.
- 19 CSR 10-33.010 Reporting Patient Abstract Data by Hospitals and Ambulatory Surgical Centers: (19) Public health authorities and coinvestigators receiving data shall be informed by the department of the penalty for violating section 192.067, RSMo.

How should this dataset be used?

Use of this data is restricted for statistical reporting and analysis only.

How should this dataset not be used?

Do not attempt to learn the identity of any person included in the data. Do not disclose or make use of the identity of any person or establishment discovered inadvertently and report the discovery to:

Missouri EPHT Program Manager Bureau of Environmental Epidemiology P.O. Box 570

Jefferson City, MO 65102-0570

Phone: 573-751-6102

Email: EPHTN@health.mo.gov

#### Can it be linked to other datasets?

Do not combine this data with other data for the purpose of matching records to identify individuals. Do not disclose or make use of the identity of any person or establishment discovered inadvertently and report the discovery to:

Missouri EPHT Program Manager

Bureau of Environmental Epidemiology

P.O. Box 570

Jefferson City, MO 65102-0570

Phone: 573-751-6102

Email: EPHTN@health.mo.gov

Can these data be used for commercial purposes?

Can these data be used to form a basis for additional health studies or some remediation actions?

Possibly, please refer to application and review procedures for using Missouri's Patient Abstract System Data at <a href="http://www.health.mo.gov/data/policies.php">http://www.health.mo.gov/data/policies.php</a>.

#### What are the constraints for data interpretation?

Do not imply or state, either in written or oral form, that interpretations based on the data are those of the original data sources, the Missouri State Government, the Missouri Department of Health and Senior Services, or the Centers for Disease Control and Prevention unless the data user and data sources are formally collaborating and have received written permission to do so. Acknowledge, in all reports or presentations based on these data, the original source of the data, the Missouri Department of Health and Senior Services, and the Centers for Disease Control and Prevention.

### **Data Security Information**

**Security classification system:** Contains small numbers which may allow indirect identification of patients, physicians or providers.

Security classification: Restricted

**Security handling:** Data must be stored on secure server. Additional security measures may be required. Specific security measures are available at <a href="http://www.health.mo.gov/data/policies.php">http://www.health.mo.gov/data/policies.php</a>.

# **Spatial Reference Information**

# **Spatial Domain**

### **Bounding Coordinates**

In Unprojected coordinates (geographic)

Boundary	Coordinate
West	-95.774699999999996 (latitude)
East	-89.098842000000005 (latitude)
North	40.613639999999997 (longitude)
South	35.995479000000003 (longitude)

### **Data Structure and Attribute Information**

#### Overview

**Entity and attribute overview:** These data include inpatient records which have a principal diagnosis of Anencephaly, Spina bifida (with oanencephaly), Hypoplastic left heart syndrome, Tetralogy of Fallot, Transposition of the great arteries (vessels), Cleft lip with or without cleft palate, Cleft palate without cleft lip, Hypospadias, Gastroschisis, Upper limb deficiencies, Lower limb deficiencies, Trisomy 21.

Records of transfer-to institutions have been deleted by identifying multiple records for a person using name, Social Security Number, date of birth, race, sex, hospital, medical record number, zip code, and principal diagnosis. Records were sorted by admit and discharge date and then the discharge disposition and dates were used to delete all transfer to records for that person.

Fields included in the data set are health outcome (Anencephaly, Spina bifida (with oanencephaly), Hypoplastic left heart syndrome, Tetralogy of Fallot, Transposition of the great arteries (vessels), Cleft lip with or without cleft palate, Cleft palate without cleft lip, Hypospadias, Gastroschisis, Upper limb deficiencies, Lower limb deficiencies, Trisomy 21), state of residence, county of residence, admit year, admit month, age group, sex, race, whether race/ethnicity reported, ethnicity, whether transfers excluded, exclusion method, number of monthly hospitalization events, number of average daily events, number of monthly minimum daily events, number of monthly maximum daily events.

The dataset includes hospital admittance by calendar years 2001-2006 and were developed from birth registry files for 2001-2007.

**Entity and attribute detailed citation:** <a href="http://www.health.mo.gov/data/patientabstract">http://www.health.mo.gov/data/patientabstract</a> system/index.php

# **Data Quality and Accuracy Information**

#### General

**Logical consistency report:** Zip codes are compared to state and county codes to determine consistency of geocoding.

**Completeness report:** Completeness percents on the source files from which the birth defects file was produced, for selected items, are as follows:

- Principal diagnosis: 99.9 percent complete for 2001-2009 discharge years.
- Patient name (used for unduplicating): 90-93 percent complete depending on year.
- Social Security Number (used for unduplicating): 80 percent all years.
- Race: 98 percent complete all years.
- Sex: 99.999 percent complete all years.
- Age: 99.9 percent complete all years. Reported maternal ages<11 or >50 assigned to unknown age.
- County of residence: 99.9 percent complete all years.
- Admit date: 99.999 percent complete all years.
- Zip code of residence: 99.9 percent complete all years.
- State of residence: 99.99 percent complete all years.
- Discharge disposition: 99.999 percent complete all years.
- Ethnicity: collected as part of race item in 2000, as separate item beginning in 2001; probably underreported; total count for "Hispanic" ranges from 6,490 in 2000 to 11,475 in 2009.

#### **Data Source and Process Information**

# **Process Steps**

# **Process step information**

#### **Process Step 1**

**Process description:** Hospital admission and discharge data are collected and compiled from hospitals by the Missouri Hospital Association then sent to the Missouri Department of Health and Senior Services as a SAS dataset for final editing and standardization and creation of variables used to respond to data requests and research.

**Process date:** 08/01/2010

#### **Process Step 2**

**Process description:** Using the annual discharge and vital records files for 2001-2007, the records for the birth defects file (Anencephaly, Spina bifida (with oanencephaly), Hypoplastic left heart syndrome, Tetralogy of Fallot, Transposition of the great arteries (vessels), Cleft lip with or without cleft palate, Cleft palate without cleft lip, Hypospadias, Gastroschisis, Upper limb deficiencies, Lower limb deficiencies, Trisomy 21) were selected based on admission date occurring during

2001 to 2008, the appropriate diagnoses in the principal diagnosis field, and state of residence of Missouri, and hospitals located in Missouri.

**Process date:** 08/01/2010

# **Process Step 3**

**Process description:** Once the relevant records were selected, persons with more than one record were given a common identification number using combinations of first and last name, Social Security Number, date of birth, race, sex, medical record number and admit and discharge dates.

**Process date:** 08/01/2010

# **Process Step 4**

**Process description:** Using the created ID and the admit and discharge dates and discharge disposition codes, records were deleted if they followed a transfer record and the admit date was the same as the discharge date of the transfer record and the transfer was either to:

- 1) another hospital,
- 2) a skilled nursing facility in the same hospital,
- 3) an intermediate care facility, or
- 4) another type of institution for inpatient or outpatient services.

**Process date:** 08/01/2010

# **Process Step 5**

**Process description:** Using the records that remained, the file was developed in accord with EPHT table shells to produce the requested statistics by birth defect, residence county, admit year, race, maternal age group, sex, maternal ethnicity and month of admit.

**Process date:** 08/01/2010

#### **Process Step 6**

Process description: Metadata record created for the dataset using the EPHT

Metadata Creation Tool., version 1.1.

**Process date:** 08/26/2010

# **Process Step 7**

**Process description:** Missouri Metadata record created for the dataset using the Missouri EPHT Metadata Record format then converted to .pdf. The creation of a Missouri Metadata record is completed to assist users by offering the record in a format compatible with electronic reading devices and smart phones.

**Process date:** 06/01/2011

#### **Data Distribution Information**

#### General

Resource description: XML file

**Distribution liability:** These data were provided by the Missouri Department of Health and Senior Services; the findings and conclusions based on these data are the sole responsibility of the author(s) of the study.

Although every effort has been made to ensure the accuracy of the material contained in this dataset and the Missouri EPHT Network Portal, complete accuracy cannot be guaranteed. The Missouri Department of Health and Senior Services is not responsible for any errors or misprints contained herein and cannot accept any responsibility whatsoever for loss or damage occasioned or claimed to have been occasioned, in part or in full, as a consequence of any person acting, or refraining from acting, as a result of a matter contained within the Missouri EPHT Network Portal.

#### **Distribution Point of Contact**

Person: Missouri EPHT Program Manager

**Organization:** Missouri Department of Health and Senior Services

Division of Community and Public Health Section for Environmental Public Health Bureau of Environmental Epidemiology

**Phone:** 573-751-6102 **Fax:** 573-751-6041

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Postal code: 65102-0570
County: Cole County

Address type: Physical

Address: 930 Wildwood Drive

City: Jefferson City State or Province: MO Postal code: 65109 County: Cole County

#### **Custom Order Process**

**Custom order process:** Users requesting access to record-level data should be aware that not all data elements included in the birth defects registry will be provided on data sets released to users outside the Department of Health and Senior Services. To request record level data (whether identified or de-identified) for research, a principal

investigator must submit a completed Application for Missouri Patient Abstract System Data for Research Purposes. The application requires detailed information about the study protocol, justification for all data elements requested (each data element must be related to the hypotheses), and measures to ensure the confidentiality and security of the data. All information must be clear, consistent and specific. General descriptions do not allow accurate assessment of the value of the study or the need for the data items. Release of data from vital records and/or the Patient Abstract System by the Missouri Department of Health and Senior Services is granted to an agency/institution for the sole purpose of the research project described in the protocol application. The applicant will be required to complete and sign an Agreement for Oversight. All persons that will have access to the data must be listed in the application and will be required to sign Confidentiality Pledge prior to being granted access to the study data.

It is the principal investigator's responsibility to design a valid study that would make a contribution to public health, and it is not the department's role to help refine a faulty study or a poorly described study until it meets generally acceptable scientific standards. Protocols of this nature will be rejected and further processing of such applications will be discontinued. An application will be immediately rejected if it is determined that 1) it does not clearly describe a well-designed research or epidemiologic study, 2) the data will be used for commercial or marketing purposes, or private gain, 3) being a coinvestigator would overburden the department, or 4) there is reason to believe that confidentiality of the data would be jeopardized by its release.

Researchers interested in obtaining DHSS data should first familiarize themselves with the data sets prior to designing their studies (see Data and Surveillance Systems at <a href="http://health.mo.gov/data/index.php">http://health.mo.gov/data/index.php</a>). Only those data elements related to the hypotheses and necessary for the study should be requested. The principal investigator will be notified of any discrepancy between the list of data elements requested in the research protocol and those determined by DHSS staff to be needed.

Vital Records and Patient Abstract Data custodian contact information may be found at <a href="http://health.mo.gov/data/pdf/contactus.pdf">http://health.mo.gov/data/pdf/contactus.pdf</a>.

PLEASE NOTE: Research proposals involving Patient Abstract System data are also reviewed by an independent Data Release Advisory Committee (DRAC) and submitted to the Department of Health & Senior Services (DHSS), Institutional Review Board (IRB) for review, prior to final study approval determination.

If the study/project involves linkage with another data set or contact with family, next-of-kin or acquaintance, DHSS IRB approval is required. A request for identifiable record level data for living subjects (e.g., birth records) shall also require approval by the DHSS IRB. Requests for de-identified files do not require approval by the DHSS IRB.

In addition to the protocol application, the following forms must also be completed for DHSS IRB review and approval (when applicable):

- Abstract of Protocol
- IRB Form 1 'Request for Review of Research Protocol'
- Protocol Template
- Checklist for Submission of Research/Study Protocols

If a study does not involve DRAC and/or DHSS IRB review, we suggest submitting a completed application at least two-to-three months prior to when data will be needed. Studies involving DRAC and/or DHSS IRB review generally require a longer review period, so we suggest submitting the completed application and IRB packet at least four-to-five months prior to when data will be needed. Protocol applications are reviewed on an 'as time permits' basis between other priority projects. The complexity of the requested data sets and the number of priority projects may impact the response time. Please plan accordingly.

Regardless of the duration of the study/project, approval is only for one year at a time. Annual review is required for each study for as long as Department data are held.

More information on obtaining a custom created dataset is available at <a href="http://www.health.mo.gov/data/policies.php">http://www.health.mo.gov/data/policies.php</a>

#### Metadata Reference

#### Metadata Date

Last updated: 10/23/2008

Metadata Point of Contact

Person: Missouri EPHT Program Manager

**Organization:** Missouri Department of Health and Senior Services

Division of Community and Public Health Section for Environmental Public Health Bureau of Environmental Epidemiology

**Phone:** 573-751-6102 **Fax:** 573-751-6041

Telecommunications Device or Teletypewriter (TDD/TTY) phone: 800-669-8819

Email: EPHTN@health.mo.gov

Address type: Mailing

Address: PO Box 570
City: Jefferson City
State or Province: MO
Postal code: 65102-0570
County: Cole County

**Address type:** Physical

Address: 930 Wildwood Drive

City: Jefferson City State or Province: MO Postal code: 65109 County: Cole County

# **Metadata Access Constraints**

Access constraints: None Use constraints: None

Metadata Standards

Standard name: FGDC Content Standard for Geospatial Metadata